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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,646	08/02/2001	Shinichi Ayabe	JKM-001	5225

20374 7590 08/17/2004

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WASHINGTON, DC 20006

EXAMINER
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KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action****Application No.**

09/890,646

**Applicant(s)**

AYABE ET AL.

**Examiner**

Russell Kallis

**Art Unit**

1638

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): New Matter.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 35,39 and 47-54.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☒ The drawing correction filed on 8/02/01 and 7/20/04 is a) ☒ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 2. NOTE: Newly filed claims 47-51, drawn to a polynucleotide encoding the amino acid of SEQ ID NO: 2, a variant thereof, a polynucleotide complementary thereto, or a polynucleotide complementary to SEQ ID NO: 1, raise new issues of 112 1st paragraph written description and enablement. The variants of SEQ ID NO: 2 or the complementary strands of SEQ ID NO: 1 of unspecified length, or the complementary strands of the polynucleotides encoding SEQ ID NO: 2, either of full length or of unspecified length, as claimed are not described, and therefore do not meet the written description requirement under 35 U.S.C. 112 1st paragraph. Further, a method for producing 2-hydroxyisoflavone synthase using a complementary polynucleotide, either in its' entirety or of some length other than full length, rather than using the coding strand would not encode a 2-hydroxyisoflavone synthase, and therefore is not enabled under 35 U.S.C. 112 1st paragraph. Furthermore, since Applicant has not described the variants of SEQ ID NO: 2, Applicant has not taught how to make those variants of SEQ ID NO: 2 that would encode a 2-hydroxyisoflavone synthase without resorting to undue trial and error experimentation.

Continuation of 5. does NOT place the application in condition for allowance because: Although Applicant has cancelled all but Claims 35 and 39 from the previous office action, Claims 35 and 39 remain rejected under 35 U.S.C. 112 1st paragraph for reasons of record and for reasons addressed supra. Further, Claim 39 remains rejected under 35 U.S.C. 102(b) for reasons of record. The method does not state that the host cells are transgenic or that the protein produced is recombinant, and thus the claim reads upon the culturing of untransformed cells of *Glycyhiza* that contain SEQ ID NO: 1 and the crude extract that comprises the 2-hydroxyisoflavone of SEQ ID NO: 2.

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~180~~ 1638

